SIEMENS Healthineers

CLINITEK Status®+

Analyzer

Operator's Guide

For Self-Test

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The information in this operator's guide was correct at the time of printing. However, Siemens Healthcare Diagnostics continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

If the system is used in a manner differently than specified by Siemens Healthcare Diagnostics, the protection provided by the equipment may be impaired. See warning and hazard statements.

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1 Introduction

The introduction explains how to get started, unpack, and install your CLINITEK Status®+ analyzer. The introduction also includes an overview of the analyzer.

Intended Use

The CLINITEK Status+ Urine Chemistry Analyzer is a portable, easy to use analyzer. It is designed to read only Siemens Healthcare Diagnostics Reagent Strips for Urinalysis.

Tests performed using the CLINITEK Status+ analyzer are intended for *in vitro* diagnostic use only and for self-test.

This analyzer is intended for the measurement of the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, and Urobilinogen.

These measurements are used to assist diagnosis in the following areas:

- Kidney function
- Urinary tract infections
- Metabolic disorders (such as diabetes mellitus)
- Liver function

Summary and Explanation

The urinalysis strips measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if further testing is needed.

How This Guide is Organized

Section	Description
1– Introduction	(This chapter). It describes the intended use of the analyzer and how to unpack and install the analyzer.
2– Using CLINITEK Status+ For Self Test	It describes how to perform a Quick Test with a urinalysis strip, view test results, and perform basic maintenance and troubleshooting tasks.
Appendices A–F	The appendices include reference information related to analyzer safety, support, supplies and equipment, analyzer design specifications, symbols used in packaging, and a glossary of commonly used terms.

Getting Started

This section provides information about how to unpack and install your CLINITEK Status+ analyzer.

Unpacking the CLINITEK Status+ Analyzer

The CLINITEK Status+ analyzer is delivered in 1 carton.

To unpack your CLINITEK Status+ analyzer, perform the following steps:

1. Carefully remove the contents of the shipping carton.

   Note Retain the shipping carton and packing materials, which offer the best protection against damage if you need to ship the analyzer.

2. Inspect the carton and contents for visible signs of damage.

   If the analyzer appears damaged, immediately file a complaint with the carrier.

3. Remove each wrapping and verify that you have the following items (see *Figure 1-1*):

   - CLINITEK Status+ analyzer
   - Power supply adaptor and AC power cord

   Note If the power cord is not the style you need, contact your local technical support provider. See *Appendix B, Support Information*.

   - Test table (tray that holds the test table insert)

CAUTION
Do not touch the white calibration bar on the test table. Damage to the calibration bar could affect the test results.

   - Test table insert (where urine strip is placed)
   - Paper roll

   Note You also can print on label stock. For information about how to order label rolls, see *Appendix C, Orderable Supplies*.

- Depending on the analyzer model you received, you also could have a Warranty Registration Card, Unpack and Installation Guide, and Quick Reference Card.

Figure 1-1: CLINITEK Status+ Analyzer Components

1	CLINITEK Status+ Analyzer
2	Paper roll
3	Power supply adaptor and AC power cord (Figure shows US version)
4	White calibration bar
5	Test table (tray that holds the test table insert)
6	Test table insert (where urine strip is placed)

Assembling the CLINITEK Status+ Analyzer

After you unpack the analyzer components, you can assemble and connect them.

To assemble the CLINITEK Status+ Analyzer components, perform the following steps:

1. Place the analyzer on a level work surface where the temperature and humidity are fairly constant.

CAUTION
The best temperature for using the analyzer is between 22–26°C (72–79°F). Do not place the analyzer outdoors or near windows, ovens, hot plates, or radiators.

2. Connect the appropriate end of the power cord into the power inlet socket located on the back of the analyzer (see *Figure 1-2*).

Figure 1-2: Assembling the CLINITEK Status+ Analyzer

1	Serial port
2	Power cord

3. Connect the other end of the power cord into an AC electrical wall outlet.

CAUTION
Use only the power supply adapter included with the analyzer. A different power supply adapter might damage the analyzer.

Inserting the Batteries (optional)

To power the CLINITEK Status+ Analyzer by batteries (optional), perform the following steps:

1. Place the analyzer on its side.
2. Remove the battery cover on the bottom of the analyzer by pressing down on the tab and pulling out the cover.
3. Place 6 new alkaline AA-size batteries into the battery compartment.
4. Place the battery cover back on the compartment and turn the analyzer back on its base.

CAUTION
Do not use batteries in the analyzer if you attach the analyzer to a CLINITEK Status connector. Leaving the batteries in the battery compartment may corrode the batteries.

Inserting the Test Table and Test Table Insert

To insert the test table and test table insert, perform the following steps:

1. Insert the test table into the analyzer by holding it by the end opposite the white calibration bar and with the white bar facing up.

2. Push the test table into the analyzer, pushing it in just over halfway.

CAUTION

Do not push the test table fully into the analyzer. The test table may become jammed and prevent the use of the analyzer.

Do not touch the white calibration bar on the test table. Damage to the calibration bar could affect the test results.

3. Place the test table insert into the test table (see *Figure 1-3*).

Figure 1-3: The Test Table and Test Table Insert

Loading the Printer Paper

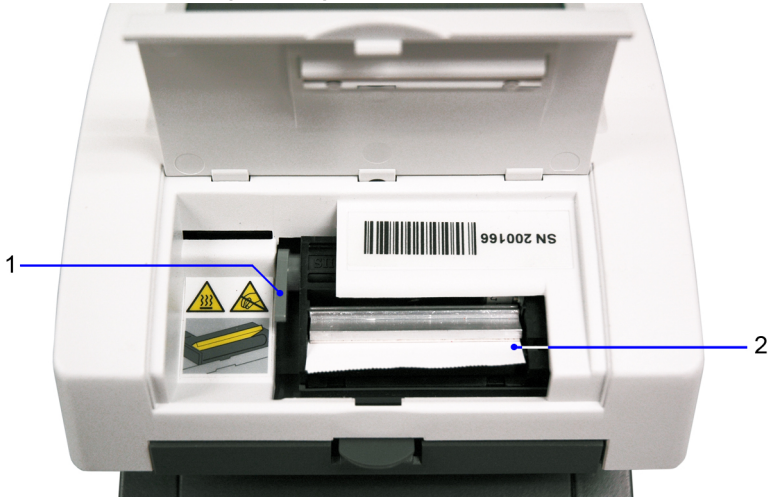
The analyzer uses ordinary thermal paper as provided, or label stock. For more information about ordering supplies, see *Appendix C, Orderable Supplies*.

To load the printer paper or label roll, perform the following steps:

1. With the back of the analyzer facing you, open the printer cover by pulling up on the tab.
2. Open the paper roll compartment cover by pressing down on its tab and pulling out the cover.
3. Lift the paper holding arm into the open, upright position.
4. Place the new paper roll into the printer paper compartment with the paper unrolling from underneath and toward the compartment wall.
5. Feed the paper up along the wall and through the printer until you have approximately 10 cm (or 4 inches) of paper through the printer.
6. Feed the edge of the paper through the printer cover.
7. Push the paper holding arm down in the closed position (see *Figure 1-4*).
8. Close the paper roll and printer covers by clicking them into position.

Note By default, the analyzer automatically prints the test results.

Figure 1-4: Printer Paper Compartment



1	Paper holding arm
2	Printer paper

Powering On/Off

If you power on the analyzer for the first time, the Start Up Wizard prompts you through a set-up procedure.

To power on the analyzer, perform the following steps:

1. Press the on/off button on the front of the analyzer.
2. The analyzer runs a diagnostic test each time you power on the analyzer.

To power off the analyzer, perform the following steps:

1. Before you power off the analyzer, always ensure that no strip is on the test table and that the table and insert are clean.

2. Press the on/off button for at least 2 seconds.

   The analyzer pulls in the test table. If no strip is on the test table, the test table door closes and the analyzer powers off.

   If a strip is still on the test table, the analyzer pushes out the test table and powers off. The test table remains out.

   To pull the test table into the analyzer, power on the analyzer, remove the strip on the test table, and then power off the analyzer.

CAUTION

Do not push the test table fully into the analyzer. The test table might become jammed and prevent the use of the analyzer.

Hardware Overview

The CLINITEK Status+ analyzer consists of the following hardware components:

- Touch screen display
- Test table
- Printer
- Connections and power
- Memory card slot

Touch Screen Display

You interact with the CLINITEK Status+ analyzer through an integrated touch screen display. The touch screen displays messages, options, and requests for information. You respond by selecting a button or an area on the screen (see *Figure 1-5*).

CAUTION
Do not use anything hard or pointed on the touch screen. It might damage the screen.

Figure 1-5: Touch Screen Display

Test Table

All testing takes place on the test table.

1. Place the strips on the test table insert.
2. The analyzer pulls in the test table partially for calibration and then pulls in the test table completely to read and test the strip.
3. When the test finishes, the test results display on the screen.

Printer

An internal thermal printer prints the test results.

Connections and Power

Connect the analyzer into an electrical outlet to use on a benchtop or sturdy tabletop, or use batteries so you can freely move the analyzer from one testing location to another.

Software Overview

The CLINITEK Status+ analyzer user interface consists of a touch screen with an onscreen alphanumeric keyboard.

Touch Screen

Use the **Select Ready** screen to configure the analyzer, run tests, recall results, and navigate to any point in the software (see *Figure 1-6*).

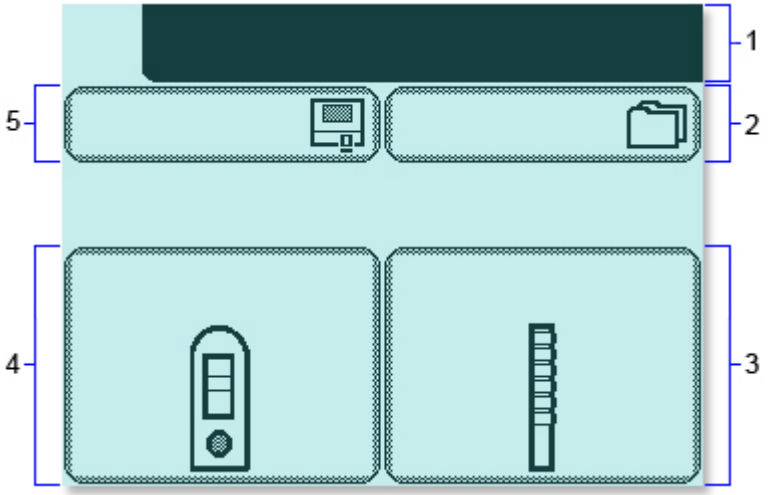
The **Select Ready** screen contains the following elements:

- **Title bar** Contains the current screen name, date, and time.
- **Selection area** Includes Instrument Set Up, Recall Results, and Strip Test.

For a complete list of icons with their descriptions, see *Appendix E, Symbols*.

Note Depending on the screen that displays, when the analyzer is idle for a period of time, the analyzer returns to the **Select Ready** screen.

Figure 1-6: Select Ready Screen



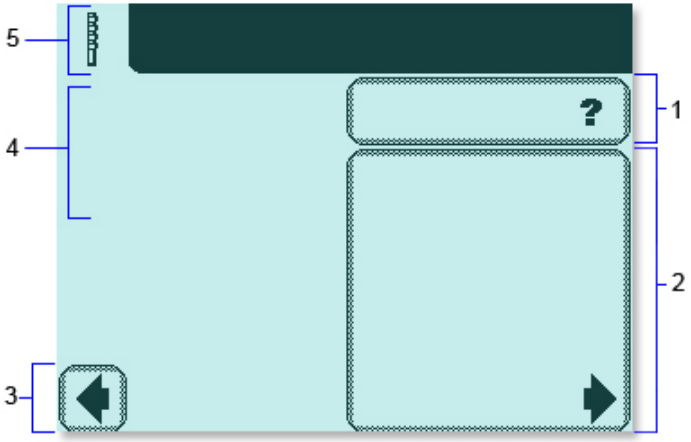
1	Title bar
2	Recall Results
3	Strip Test

4	Cassette Test*
5	Instrument Set Up

* For Professional use only. Not for self-test.

Each subsequent screen can display an icon in the upper left corner to indicate an analyzer mode or action (see *Figure 1-7*). For example, the battery icon indicates that the analyzer is powered by batteries. A screen also can display buttons, instructions, alert messages, and error messages.

Figure 1-7: Screen Elements

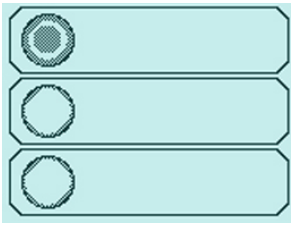
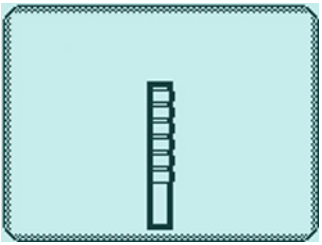


1	Help
2	Selection Area
3	Button
4	Instructions
5	Icon

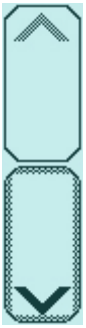
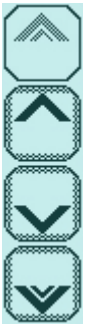
Tap the screen lightly in a selection area or button to select an option or button, or to navigate in a list of items.

CAUTION
Do not use anything hard or pointed on the touch screen. It might damage the screen.

The CLINITEK Status+ analyzer provides several screen elements: option, area, button, arrow, and double arrows.

Screen Element	Example	Description
Option		Round option buttons display on screens where you select an option. The option button with a filled circle is the current selection. For example, **Sound on**, **Sound off**, and **Key clicks only** are instrument setup options. To change your selection, select an option button with an unfilled circle. The newly selected circle (round option button) is highlighted. In the example, the **Sound on** option is selected.
Selection Area		Selection areas enclosed in boxes on the screen indicate functions that you can select. Select a boxed area to activate that function. For example, **Strip Test**. An area varies in size. For example, the boxes on the **Select Ready** screen are large areas.

Screen Element	Example	Description
Button		Several buttons display at the bottom of the screens, which include **Select** and **Done**. To navigate the screens, the analyzer displays left and right arrow buttons. To move to the previous screen, select **Previous** (left arrow). To move to the next screen, select **Next** (right arrow).

Screen Element	Example	Description
Arrow		Select the up and down arrows on the right side of the screen to scroll through the items in a list and highlight an item on the left side of the screen. Select the **Select** button to confirm your selection and move to the next screen. When an arrow is highlighted, you can use it to scroll. When an arrow is dimmed, you are viewing the first item or last item in the list, and cannot scroll beyond that page. **Note** When an item in a list displays a highlighted bar, you can select that item.
Double Arrows		When double arrows display on the screen, you select these arrows to move to the top or bottom of the page. When a double arrow is highlighted, you can use it to scroll. When a double arrow is dimmed, you are viewing the first page or last page of the list, and cannot move beyond that page.

2 Using CLINITEK Status+ for Self Test

The CLINITEK Status + analyzer is used to test urine. Your doctor may have asked you to use this analyzer to monitor your health. When using this analyzer, note the following:

- Do not change treatment or make any decision of medical relevance without first consulting a healthcare professional.
- There is the possibility that a result is incorrect, for example, false positive or false negative results.
- Use only Siemens Reagent Strips for Urinalysis designated for self-test.
- Do not use the analyzer in temperatures below 18°C or above 30°C. For more information, see *Environmental Specifications*, page 54.

Before You Begin

Make sure you have the following items before starting the test:

- Siemens Healthcare Diagnostics reagent test strip
- Clean dry container for the urine
- Paper towel to blot strip
- Gloves

Before running a test:

- You should test fresh urine samples within 2 hours of collection.
- Make sure you have enough urine to cover all of the test pads on the strip.
- Refrigerated urine samples must be brought to room temperature (20–30°C).
- Do not change any of the analyzer's default settings.
- Check that the test table and table insert are clean.

  Note You should clean the test table and table insert weekly or more frequently to maintain the analyzer.

Performing a Quick Test

You can perform a Quick Test with a urinalysis strip. Each time you run a test, the analyzer calibrates automatically to make sure the test results are accurate. You cannot cancel a test before the analyzer finishes the test.

Performing a Urinalysis Strip Quick Test

Perform the following procedure to test a strip.

BIOHAZARD
Wear personal protective equipment, such as gloves. For recommended precautions when you work with urine, see *Appendix A, Safety Information*.

Preparing a Urinalysis Strip Quick Test

Before you perform a urinalysis strip Quick Test, prepare the analyzer and the strip.

For more information about the use and storage of urinalysis strips, see the urinalysis strip instructions for use insert.

Note The analyzer automatically detects the type of Siemens test strip. Therefore, you do not need to select the strip type from a menu.

To prepare a urinalysis strip Quick Test, perform the following steps:

1. On the **Select Ready** screen, select **Strip Test**.
2. Make sure the reagent strip holder faces upward in the test table insert (see *Figure 2-1*).
3. Have the urinalysis strip and paper towel ready.

Figure 2-1: Urinalysis Strip Holder Position

Running a Urinalysis Strip Quick Test

To run a urinalysis strip Quick Test:

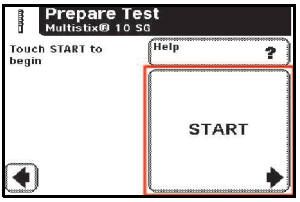
Note After you select **START**, you have 8 seconds to dip the strip in the urine sample and place the strip in the test table channel. Do not dip the strip before you select **START**.

1. Select **START**.

   The **Prepare Test** screen displays steps on how to perform the test (see *Figure 2-2*). A timer displays the amount of time remaining that you have to complete the task.

   Note To display the strip testing steps on the screen, select **Help**.

Figure 2-2: Prepare Test Screen



2. Dip the reagent strip in the urine sample and wet all the pads.

   Note Be sure to use the proper dipping technique described in steps 3–6.

3. Immediately remove the strip from the urine.

4. Drag the edge of the strip against the side of the sample container as you remove it.

5. Blot the edge of the strip on a paper towel to remove the excess urine.

6. Place the strip in the test table channel with the test pads facing up.

7. Slide or push the strip to the end of the channel. Do not touch the pads on the strip.
    - After the 8-second countdown ends, the analyzer pulls in the test table and strip, and then calibrates.

Note Each time you run a test, the analyzer calibrates.

CAUTION

Do not push or pull the test table because the calibration might fail or the movement might cause table positioning errors.

Do not move or bump the table while the analyzer calibrates. The calibration might fail.

- After the calibration finishes, the analyzer starts analyzing the strip, and the **Analyzing** screen displays.
- A timer counts down the time remaining in the strip analysis process. After the countdown ends, the analyzer displays the first page of the test results on the **Results** screen.
- The results display on the screen for 2 minutes. Then, the display returns to the **Select Ready** screen.
- The test table and strip move out of the analyzer.

Viewing the Urinalysis Strip Quick Test Results

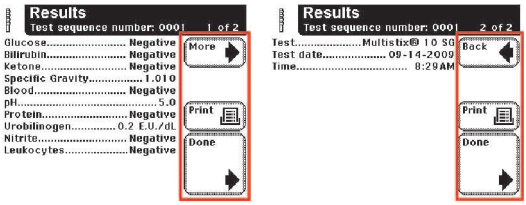
The first page of test results display on the **Results** screen. The analyzer prints the results automatically (see *Figure 2-3*).

The test results printout could include any of the following information:

- Date
- Time
- Test number
- Results

- Sample interference notes (To be used by your healthcare professional.)

Figure 2-3: Test Results



Completing the Urinalysis Strip Quick Test

To complete the urinalysis strip Quick Test, perform the following steps:

1. Remove the used urinalysis strip from the test table and dispose of it as directed by your healthcare professional.
2. Wipe the table insert, if necessary (see *Weekly Cleaning of the Test Table and Test Table Insert*, page 31).
3. Report the results to your healthcare professional.
4. Select **Done** to complete the test.

   The results display on the screen for 2 minutes.

Quality Control

Quality Control (QC) testing helps ensure that the urinalysis strips are performing correctly and that the analyzer is accurately reading them. QC also helps detect errors that result from user techniques.

Contact your healthcare professional for guidance on QC.

Maintenance

Clean the test table and table insert weekly or more frequently, if necessary, to maintain the analyzer for the following reasons:

- Ensure that the analyzer operates properly
- Provide accurate test results
- Prevent contamination
- Avoid bacterial growth

Weekly Cleaning of the Test Table and Test Table Insert

BIOHAZARD
Wear personal protective equipment, such as gloves. For recommended precautions when you work with urine, see *Appendix A, Safety Information*.

Clean the test table and test table insert on a weekly basis or more frequently if necessary, to ensure test result accuracy and prevent contamination and bacterial growth.

To clean the test table and test table insert, perform the following steps:

1. Remove the test table by pulling it slowly out of the analyzer.
2. Lift the table insert to remove it from the test table.
3. Drain the drip tray, if necessary.
4. Wet a cotton-tipped stick with water and thoroughly scrub the test table and table insert, except for the white calibration bar.
5. Rinse both sides of the table insert and test table under running water.
6. Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.

CAUTION
Do not to scratch the white calibration bar. Marks and stains could cause inaccurate test results. Severe marks can cause errors.

7. Examine the white calibration bar on the test table for dirt or discoloration.

CAUTION
Do not touch the calibration bar while you examine it or after you clean it. Your fingerprints or lint on the bar could cause unreliable test results. When you examine the white calibration bar, do it carefully under good lighting.

- If the white calibration bar appears clean and unmarked, go to step 9.
- If the bar appears dirty or discolored, clean the calibration bar, as described in *Cleaning the White Calibration Bar*, page 32.

8. Insert the test table, pushing it in more than halfway into the analyzer.

CAUTION
Do not push the test table fully into the analyzer. The test table might jam and prevent you from using the analyzer.

9. Insert the table insert.

Cleaning the White Calibration Bar

For the CLINITEK Status+ analyzer to perform as intended and to provide reliable test results, the white calibration bar on the test table needs to be clean and not discolored.

Siemens recommends that you check the calibration bar for cleanliness weekly, and when you clean the test table. Also, check the calibration bar for cleanliness if you remove a strip from inside the analyzer. Clean the calibration bar, only if needed.

BIOHAZARD
Wear personal protective equipment, such as gloves. For recommended precautions when you work with urine, see *Appendix A, Safety Information*.

To clean the white calibration bar, perform the following steps:

1. Remove the insert from the test table.

2. Remove the test table by pulling it slowly out of the analyzer.
3. Drain the drip tray, if necessary.
4. Examine the white calibration bar on the test table for dirt or discoloration.

CAUTION
Do not touch the calibration bar while you examine it or after you clean it. Your fingerprints or lint on the bar could cause unreliable test results. Examine the white calibration bar carefully under good lighting.

5. If the white calibration bar appears clean and unmarked, perform the following steps:
   a. Re-insert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upward.
   b. Push the test table firmly but slowly, just over halfway into the analyzer.

CAUTION
Do not push the test table fully into the analyzer. The test table might jam and prevent you from using the analyzer.

   c. Insert the test table insert.
6. If the white calibration bar appears dirty or discolored, perform the following steps:
   a. Wet a new cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bar.

CAUTION
Do not scratch the white calibration bar. Marks and stains could cause inaccurate test results. Severe marks can cause errors.
Do not use solvents of any kind to clean the calibration bar. They could destroy the bar.

   b. Allow the calibration bar to air dry.

c. Inspect the surface for dust, foreign material, scratches, or scuffs.

   If you cannot completely clean the calibration bar or if the bar has scratches, you may need to order a new test table. Contact your healthcare professional.

d. Insert the test table and table insert, as described in step 5.

Disinfecting the Test Table and Table Insert

Disinfect the test table and the test table insert as necessary. Use a recommended disinfection solution for the following reasons:

- Prevent contamination
- Prevent bacterial growth
- Avoid damage to the test table and insert

To disinfect the test table and the table insert, perform the following steps:

1. Prepare one of the following solutions in a tall, narrow container (such as an empty Multistix® bottle) to a depth of about 10 cm (or 4 inches):
   - **Household Bleach (5% sodium hypochlorite)** use as full strength or dilute with water to as much as 1:20 (mix 5 mL bleach with 95 mL water for a total of 100 mL).
   - **Isopropyl Alcohol (70%–85%)** use as full strength.
   - **PRESEPT ™ , Cidex®, Theracide®, or Amphyl® solution** prepare according to the product directions.

CAUTION
Any solutions other than the ones mentioned might damage the test table and the table insert.

2. Remove the table insert from the test table.
3. Remove the test table by pulling it slowly out of the analyzer.
4. Drain the drip tray, if necessary.

5. Place the table insert and test table into the solution, with the white calibration bar on the test table above the liquid level.

CAUTION
Be sure the cleaning solution does not come in contact with the white calibration bar. Cleaning solution can discolor or damage the calibration bar.

6. Soak the test table and the table insert for a minimum of 2 minutes and a maximum of 10 minutes.

CAUTION
Do not soak the test table and the table insert longer than 10 minutes. You could damage them.

7. Rinse the test table and the table insert thoroughly with water.

CAUTION
Rinse away all the solution residue, as any remaining solution might affect the test strips.

8. Dry the test table and the table insert thoroughly with a soft cloth, except for the white calibration bar.
9. Insert the test table and the table insert in the analyzer, as described in *Weekly Cleaning of the Test Table and Test Table Insert*, page 31.

Cleaning the Outside of the Analyzer

Always keep the outside of the CLINITEK Status+ analyzer clean and free of dust.

BIOHAZARD
Wear personal protective equipment, such as gloves. For recommended precautions when you work with urine, see *Appendix A, Safety Information*.

To clean the outside of the analyzer, perform the following steps:

1. Power off the analyzer by pressing the on/off button for 2 seconds.

2. Wipe the outside (including the display) with a damp (not wet) cloth and a mild detergent.

CAUTION

Do not use any type of solvent, oil, grease, silicone spray, or lubrication on the analyzer.
Do not spray glass cleaner directly onto the screen.
Prevent liquid from entering inside the printer compartment.
You could damage the analyzer or the printer.

3. Disinfect the display with the same solution you use for the test table, as described in *Disinfecting the Test Table and Table Insert*, page 34.
   a. Wipe the solution on the display and let it remain for 10 minutes.
   b. Wipe the display with a clean cloth dampened with water.
   c. Dry the display with a clean cloth.

Changing the Batteries

The CLINITEK Status+ analyzer allows you to run approximately 100 tests from a set of batteries. To achieve this, the Power Save feature is always activated when you power the analyzer by batteries.

Note The test result printout might be lighter when you use batteries to power the analyzer.

If you do not use the analyzer in 3 minutes when it is battery-powered, it automatically powers off.

When you power the analyzer by batteries, a battery power icon displays near the title bar. The icon contains up to 4 vertical bars to indicate the amount of power left in the batteries.

When the batteries run low, the testing continues, but a `Low battery` message displays on the **Select Ready** screen.

Note If you do not change the batteries and the power level becomes too low to power the analyzer, a `Critical low battery` message displays. You cannot run a test until you replace the batteries.

The CLINITEK Status+ analyzer uses 6 AA-size batteries.

To change the batteries, perform the following steps:

1. Remove the test table by pulling it slowly out of the analyzer.
2. Drain the drip tray, if necessary.
3. Place the analyzer on its side.
4. Remove the battery cover on the bottom of the analyzer:
    a. Press down on the tab.
    b. Pull out the battery cover.
5. Replace the batteries:
    a. Remove the current batteries.
    b. Place 6 new AA-size batteries into the analyzer.
6. Insert the battery cover.
7. Turn the analyzer back onto its base.
8. Insert the test table and table insert.

Troubleshooting

If a problem occurs, in most cases, an error number with an explanation of the problem displays on the **Select Ready** screen. If a problem persists, write down the error number that displays and contact your healthcare provider for assistance.

If you think a Siemens urinalysis strip is causing the problem, see its product insert for troubleshooting information.

After an error occurs, if you power off the analyzer, be sure to retest the sample that was in progress. When you power on the analyzer, restart the test.

Error Messages

Error messages display to help you when the CLINITEK Status+ analyzer detects an issue that needs your attention. The type of error message depends on the importance of the problem and the mode in which you use the analyzer. The error messages include the following types:

- Errors that disable the analyzer
- Errors that require correction
- Advisory error messages
- Results alerts

Note For a list of errors and advisory messages and how to correct them, see *Common Error Messages*, page 39.

Errors That Require Correction

Certain errors must be corrected to enable testing. These errors do not prevent you from using other analyzer functions. An error message displays with a corrective action. Perform the corrective action to enable testing.

Advisory Error Messages

An advisory error message is of less importance, and displays on the **Select Ready** screen the next time the **Select Ready** screen displays. When you perform the corrective action, the analyzer removes the message from the screen.

If more than one advisory error occurs, when you clear the first advisory error message, the analyzer displays the next advisory error message.

Results Alert

If an error occurs during testing and the test cannot continue because of the error, a message displays on the **Results Alert** screen. The results alert error message provides details about the error and shows that the test was canceled. The analyzer pushes out the test table so that you can dispose of the urinalysis strip. Do not reuse the strip.

Common Error Messages

The following table contains common error codes and descriptions, with their possible causes and actions you can take to resolve them.

Note If you cannot troubleshoot an error, contact your healthcare professional.

Error Code	Error Message	Action
E01 or E23	Low battery power	The battery level is too low to power the analyzer. Replace the batteries. See *Changing the Batteries*, page 36.
E10 or E48	Loss of test results	1. Power off the analyzer by pressing the on/off button for 2 seconds. 2. Power on the analyzer by pressing the on/off button. 3. Repeat the test.

Error Code	Error Message	Action
E11	Failure of test table	The test table is positioned improperly. 1. Make sure that the test table is in place. 2. Move the test table in or out of the analyzer slightly to reposition the test table. 3. If the error remains, with the analyzer powered on, disconnect the power cord from the back of the analyzer and connect it back in. Press the on/off button to power on the analyzer.
E24	No printer paper	Replace the printer paper by using any of the following instructions: 1. On the screen, select **Error Report** to view the instructions. 2. Lift the printer paper compartment cover to view the instructions inside. 3. See *Loading the Printer Paper*, page 13.
E25, E64, or E65	Failure of automatic calibration	Clean the calibration bar. See *Cleaning the White Calibration Bar*, page 32.
E27	Setup failure	1. Power off the analyzer by pressing the on/off button for 2 seconds. 2. Power on the analyzer by pressing the on/off button.

Error Code	Error Message	Action
E28	Printer error	1. Lift the printer cover. 2. Push the paper holding arm back into position. For the location of the paper holding arm, see *Loading the Printer Paper*, page 13.
E50	Incorrect strip type or tilted strip	Verify that you correctly placed the strip on the test table insert and that you used a Siemens Reagent Strip for Urinalysis.
E54	Cassette Test selected but strip detected*	Repeat the test (see *Performing a Urinalysis Strip Quick Test*, page 26).
E57	Missing strip or cassette*	Repeat the test and ensure that you correctly position the strip on the test table (see *Performing a Urinalysis Strip Quick Test*, page 26).
E58	Misplaced strip	1. Repeat the test and ensure that you correctly position the strip on the test table (see *Performing a Urinalysis Strip Quick Test*, page 26). 2. If the error remains, examine the test table insert to ensure that the small, white line located near the tip of the strip (on the strip side of the insert) is present and not damaged. 3. If this line is damaged, contact your healthcare professional.
E59	Inverted strip positioned on the test table	Repeat the test with a fresh strip and ensure that the strip is correctly positioned on the test table (see *Preparing a Urinalysis Strip Quick Test*, page 26).

Error Code	Error Message	Action
E60	Tilted strip	Repeat the test with a fresh strip and ensure that the strip is correctly positioned on the test table (see *Preparing a Urinalysis Strip Quick Test*, page 26).
E61	Dry strip	Repeat the test with a fresh strip and ensure that the strip has been in contact with the sample (see *Preparing a Urinalysis Strip Quick Test*, page 26).
E62	Light Ingress	Too much light is reflecting on the analyzer. Move the analyzer to a location with lower lighting.
E69	Strip quality problem	When the analyzer performed a quality check, the strip quality failed. The quality check detects whether the strip was compromised due to humidity exposure. 1. Remove the defective strip and discard. 2. Repeat the test with a fresh strip that meets the quality requirements.

* Disclaimer: The hCG cassette test is not for self-test.

Troubleshooting the Analyzer Operation

The following table contains the analyzer operation icons that can display near the title bar on the **Select Ready** screen when an operation issue occurs.

Icon	Description	Action
	Low Battery Power	Displays on the **Select Ready** screen, indicating that the battery power level is low. An advisory message also displays when the battery power level is low. The power level decreases while the testing continues. If the battery level falls too low to power the analyzer, you cannot run a test until you replace the batteries. • Replace the batteries. For instructions, see *Changing the Batteries*, page 36.
	No Printer Paper	Displays on the **Print Help** button on the **Select Ready** screen, indicating that the printer is out of paper or a label roll. An advisory message also displays. • Replace the empty paper or label roll with a new one, as instructed in *Loading the Printer Paper*, page 13.

Appendix A: Safety Information

Read the following safety information for your protection.

Protecting Yourself from Biohazards

The established guidelines for handling biohazards are based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use these safety guidelines for general information only.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood, blood products, and other body fluids.

Recognizing Sources of Contamination

When you handle potentially infectious agents, keep in mind the following major sources of contamination:

- Hand-to-mouth contact
- Hand-to-eye contact
- Direct contact with superficial cuts, open wounds, and other skin conditions that might permit absorption into subcutaneous skin layers
- Splashes or aerosol contact with skin and eyes

Preventing Contamination

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the analyzer that have contact with body fluids such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.

- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats, or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the analyzer sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipette any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

References

1. Centers for Disease Control. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. 1988. MMWR, 37:377-382, 387, 388.
2. Clinical and Laboratory Standards Institute (formerly NCCLS). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3. [ISBN 1-56238- 567-4].
3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

Appendix B: Support Information

This appendix provides the technical support information for your CLINITEK Status+ analyzer.

Installation Details

Please record the following information and keep this sheet in your laboratory for future reference.

Date of Installation _____

Serial Number _____

Limitations of Liability

In no event shall Siemens be liable for indirect, special or consequential damages, even if Siemens has been advised of the possibility of such damages.

For warranty service, contact your local technical support provider for assistance, instructions, repair, or replacement of this instrument.

Legal Information

To contact a legal representative for Siemens Healthcare Diagnostics in the European community, contact the Siemens Authorized Representative.

When to Contact Technical Support

Contact your healthcare provider if the following circumstances occur:

- An error message continues to display after you perform the steps as described on the screen and in *Troubleshooting, page 38*.
- You need additional assistance about an analyzer problem.
- The problem is beyond the scope of this guide.
- You cannot solve the problem and an analyzer failure is apparent.

Also, our local technical support providers are available to help you. To order supplies or replacement parts, or to obtain service, contact your local technical support provider or visit siemens-healthineers.com/poc.

IVD CE 0197

Origin GB
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5097 USA

EC REP

Siemens Healthcare Diagnostics
Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland
siemens-healthineers.com/poc

Appendix C: Orderable Supplies

This appendix contains the supplies you can order from your local technical support representative.

Product Description	*SMN*
CLINITEK Status+ Analyzer - English	11317309

Supplies

The following supplies are available for your CLINITEK Status+ analyzer. Contact your local technical support representative to order the supplies.

Product Description	*SMN*
Thermal Printer Paper (5 rolls)	10314709
Label paper (5 rolls)	10324219

Siemens Reagent Strips for Urinalysis

Product Description	*SMN*	*REF*	*Product Code*
Multistix 10 SG [25 LATIN]	10319565	03783489	A2292C52
Multistix 10 SG [100 NORDIC]	10322360	05328339	A2300A29
Multistix 10 SG [100 GER]	10315394	01526748	A2300D18
Multistix 8 SG [10 E/F/G/D]	10320335	04200746	A2304C51
Multistix 8 SG [100 SCAND]	10322217	05258055	A2304D29
Multistix 7 [NORDIC]	10314818	01211267	A2305D29
Multistix 5 [50 NORDIC]	10326466	07500392	A2308C29
Multistix GP 25 [UK/SPAN]	10321054	04624902	A2283J01
CLINITEK Microalbumin 9 [25 E/F/G/I]	10285741	06916863	A2093C51
CLINITEK Microalbumin 2 [25 NORDIC]	10318739	03330964	A2083C29

Replacement Parts

Replacement parts are available for your CLINITEK Status+ analyzer. Contact your local technical support representative to order the following parts:

Description	*SMN*
Power Supply - UK	10378633
Power Supply - European	10378634
Test Table	10309067
Test Table Insert	10309068

Documentation

The following documentation is available for your CLINITEK Status+ analyzer. Contact your local technical support representative to order any documentation.

Description	*Part Number*
CLINITEK Status+ Analyzer Operator's Guide for Self-Test (This guide) - (printed manual, multiple languages available)	11317315

Description	*Part Number*
CLINITEK Status+ Analyzer for Self-Test multilingual documentation CD	11306478
CLINITEK Status+ Quick Reference Card for Self-Test (printed manual, multiple languages available)	11317276

Appendix D: Specifications

This appendix contains the analyzer specifications, tables of results, and an explanation of the analyzer's testing method.

Analyzer Specifications

This appendix summarizes the design specifications for the CLINITEK Status+ analyzer and provides summary tables of test results from the CLIA waiver and the physician office studies.

Analyzer Dimensions

Dimension	Value
Depth	272 mm (10.7 inches)
Width	171 mm (6.7 inches)
Height	158 mm (6.2 inches)
Weight	1.66 kg (3.65 lb) CLINITEK Status+ analyzer only (unpacked, without batteries or power supply)

Environmental Specifications

Specification	Value
Ambient Operating Temperature Range	18–30°C (64–86°F)
Ambient Operating Humidity Range	18–80% Relative Humidity (non-condensing)
Optimum Operating Temperature Range	22–26°C (72–79°F)
Optimum Operating Humidity Range	35–55% Relative Humidity (non-condensing) Optimum ranges ensure that the reagent results are optimized for performance. For example, at temperatures under 22°C (72°F), urobilinogen and leukocyte results might decrease, and at temperatures above 26°C (79°F), increase.
Altitude	2000 m (6562 ft)
Pollution Degree	2

Electrical Requirements

Requirement	Value
Power	9V DC, 7.2 VA
Battery Powered Operation	Size 6 AA alkaline batteries

Safety Standards

The CLINITEK Status+ analyzer is classed as a Class A computing device in accordance with Part 15 of the FCC Rules.

Note This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Safety Certifications

For safety certifications information, see the Declaration of Conformity (DoC). Contact your local technical support provider for the DoC.

Electromagnetic Compatibility (EMC)

For electromagnetic compatibility (EMC) information, see the Declaration of Conformity (DoC). Contact your local technical support provider for the DoC.

Tables of Results

The analyzer displays and prints the test results for reagent strips in the following formats:

- English Units, Conventional
- English Units, International (SI)
- English Nordic Units, Nordic Plus System

English, Units – Conventional

If you select English Conventional unit of measurement, the reagent strip tests display the following results.

Reagent Strip Tests

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for English Conventional units for reagent strips.

The results shown in the shaded areas are marked as positives, if you enabled Mark Positive Results in Instrument Set Up. They are marked by asterisks when displayed and printed, and when the CLINITEK Status+ analyzer transfers the data to a host computer.

Table D-1: English Units – Conventional, Reagent Strips

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Glucose	GLU	mg/dL	Negative	500	Negative	2+
			100	>=1000	Trace	3+
			250		1+	
Glucose (CLINITEK Microalbumin 9)	GLU	mg/dL	Negative	500	Negative	2+
			100	1000	Trace	3+
			250	>=2000	1+	4+

Test	Abbreviation	Units	Reported Results				
			Normal System			Plus System	
Bilirubin	BIL	-	Negative		Moderate	Negative	2+
			Small		Large	1+	3+
Ketone	KET	mg/dL	Negative		40	Negative	2+
			Trace		80	Trace	3+
			15		>=160	1+	4+
Specific Gravity	SG	-	<=1.005		1.020	No Difference	
			1.010		1.025		
			1.015		>=1.030		
Occult Blood	BLO	-	Negative		Small	Negative	1+
			Trace-lysed		Moderate	Trace-lysed	2+
			Trace-intact		Large	Trace-intact	3+
pH	pH	-	5.0	6.5	8.0	No Difference	
			5.5	7.0	8.5		
			6.0	7.5	>=9.0		

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Protein (Multistix PRO) (CLINITEK Microalbumin 9)	PRO	mg/dL	Negative 15 30	100 300	Negative Low 1+	2+ 3+
Protein (All other reagent strips)	PRO	mg/dL	Negative Trace 30	100 >=300	Negative Trace 1+	2+ 3+
Urobilinogen	URO	E.U./dL	0.2 1.0 2.0	4.0 >=8.0	No Difference	
Nitrite	NIT	–	Negative	Positive	No Difference	
Leukocytes	LEU	–	Negative Trace Small	Moderate Large	Negative Trace 1+	2+ 3+
Albumin	ALB	mg/L	10 30	80 150	No Difference	

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Creatinine	CRE	mg/dL	10 50 100	200 300	No Difference
Albumin: Creatinine (CLINITEK Microalbumin 2)	A:C	mg/g	< 30 Normal 30 – 300 Abnormal	> 300 High Abnormal	No Difference
Albumin: Creatinine (CLINITEK Microalbumin 9)	A:C	mg/g	Normal Dilute < 30 Normal	30 – 300 Abnormal 300 High Abnormal	No Difference
Protein: Creatinine (Multistix PRO)	P:C	mg/g	Normal Dilute Normal 150 Abnormal	300 Abnormal > 500 Abnormal	No Difference

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Protein: Creatinine (CLINITEK Microalbumin 9)	P:C	mg/g	Normal Dilute Normal 300 Abnormal 1500 Abnormal	3000 Abnormal >=5000 Abnormal	No Difference

English Units – International (SI)

If you select English International (SI) unit of measurement, the reagent strip tests display the following results.

Reagent Strip Tests

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for English SI units for reagent strips.

The results shown in the shaded areas are marked as positives, if you enabled Mark Positive Results in Instrument Set Up. They are marked by asterisks when displayed, when printed, and when the CLINITEK Status+ analyzer sends the data to a host computer.

Table D-2: English, Units – International SI, Reagent Strips

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Glucose	GLU	mmol/L	Negative	28	Negative	2+
			5.5	>=55	Trace	3+
			14		1+	
Glucose (CLINITEK Microalbumin 9)	GLU	mmol/L	Negative	28	Negative	2+
			5.5	55	Trace	3+
			14	>=110	1+	4+
Bilirubin	BIL	–	Negative	Moderate	Negative	2+
			Small	Large	1+	3+
Ketone	KET	mmol/L	Negative	3.9	Negative	2+
			Trace	7.8	Trace	3+
			1.5	>=15.6	1+	4+
Specific Gravity	SG	–	<=1.005	1.020	No Difference	
			1.010	1.025		
			1.015	>=1.030		

Test	Abbreviation	Units	Reported Results				
			Normal System			Plus System	
Occult Blood	BLD	Ery/µL	Negative		Ca 25	Negative	1+
			Trace-lysed		Ca 80	Trace-lysed	2+
			Trace-intact		Ca 200	Trace-intact	3+
pH	pH	–	5.0	6.5	8.0	No Difference	
			5.5	7.0	8.5		
			6.0	7.5	>=9.0		
Protein (Multistix PRO) (CLINITEK Microalbumin 9)	PRO	g/L	Negative		1.0	Negative	2+
			0.15		3.0	Low	3+
			0.3			1+	
Protein (All other reagent strips)	PRO	g/L	Negative		1.0	Negative	2+
			Trace		>=3.0	Trace	3+
			0.3			1+	
Urobilinogen	UBG	µmol/L	3.2		66	No Difference	
			16		>=131		
			33				
Nitrite	NIT	–	Negative		Positive	No Difference	

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Leukocytes	LEU	Leu/µL	Negative Ca 15 Ca 70	Ca 125 Ca 500	Negative Trace 1+	2+ 3+
Albumin	ALB	mg/L	10 30	80 150	No Difference	
Creatinine	CRE	mmol/L	0.9 4.4 8.8	17.7 26.5	No Difference	
Albumin: Creatinine (CLINITEK Microalbumin 2)	A:C	mg/mmol	< 3.4 Normal 3.4 – 33.9 Abnormal	> 33.9 High Abnormal	No Difference	
Albumin: Creatinine (CLINITEK Microalbumin 9)	A:C	mg/mmol	Normal Dilute <3.4 Normal 3.4 – 33.9	Abnormal > 33.9 High Abnormal	No Difference	

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Protein: Creatinine (Multistix PRO)	P:C	mg/mmol	Normal Dilute Normal 17.0 Abnormal	33.9 Abnormal > 56.6 Abnormal	No Difference
Protein: Creatinine (CLINITEK Microalbumin 9)	P:C	mg/mmol	Normal Dilute Normal 33.9 Abnormal 170 Abnormal	339 Abnormal >=566 Abnormal	No Difference

English Nordic, Units – Nordic Plus System

If you select English Nordic unit of measurement, the reagent strip tests display the following results.

Reagent Strip Tests

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for Nordic units for reagent strips.

The results shown in the shaded areas are marked as positives, if you enabled Mark Positive Results in Instrument Set Up. They are marked by asterisks when displayed, when printed, and when the CLINITEK Status+ analyzer sends the data to a host computer.

Table D-3: English Nordic, Units – Nordic Plus System, Reagent Strips

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Glucose	GLU	–	Negative	3+	Negative	2+
			1+	4+	Trace	3+
			2+		1+	
Glucose (CLINITEK Microalbumin 9)	GLU	–	Negative	3+	Negative	2+
			1+	4+	Trace	3+
			2+	5+	1+	4+

Test	Abbreviation	Units	Reported Results			
			Normal System			Plus System
Bilirubin	BIL	–	Negative		2+	No Difference
			1+		3+	
Ketone	KET	–	Negative		3+	Negative 2+
			1+		4+	Trace 3+
			2+		5+	1+ 4+
Specific Gravity	SG	–	<=1.005		1.020	No Difference
			1.010		1.025	
			1.015		>=1.030	
Occult Blood	BLD	–	Negative		1+	No Difference
			+/-		2+	
			+/- Intact		3+	
pH	pH	–	5.0	6.5	8.0	No Difference
			5.5	7.0	8.5	
			6.0	7.5	>=9.0	

Test	Abbreviation	Units	Reported Results					
			Normal System				Plus System	
Protein (Multistix PRO) (CLINITEK Microalbumin 9)	PRO	–	Negative Low 1+		2+ 3+		No Difference	
Protein (All other reagent strips)	PRO	–	Negative +/- 1+		2+ 3+		Negative Trace 1+	2+ 3+
Urobilinogen	UBG	µmol/L	3.2 16 33		66 >=131		No Difference	
Nitrite	NIT	–	Negative		Positive		No Difference	
Leukocytes	LEU	–	Negative 1+ 2+		3+ 4+		Negative Trace 1+	2+ 3+
Albumin	ALB	mg/L	10 30		80 150		No Difference	

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Creatinine	CRE	mmol/L	0.9 4.4 8.8	17.7 26.5	No Difference
Albumin: Creatinine (CLINITEK Microalbumin 2)	A:C	mg/mmol	< 3.4 Normal 3.4 - 33.9 Abnormal	> 33.9 High Abnormal	No Difference
Albumin: Creatinine (CLINITEK Microalbumin 9)	A:C	mg/mmol	Normal Dilute < 3.4 Normal	3.4-33.9 Abnormal > 33.9 High Abnormal	No Difference
Protein: Creatinine (Multistix PRO)	P:C	mg/mmol	Normal Dilute Normal 17.0 Abnormal	33.9 Abnormal >56.6 Abnormal	No Difference

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Protein: Creatinine (CLINITEK Microalbumin 9)	P:C	mg/mmol	Normal Dilute Normal 33.9 Abnormal 170 Abnormal	339 Abnormal >=566 Abnormal	No Difference

System Overview and Principles

Description of Optical System

The optical system consists of:

- six light emitting diodes (LEDs)
- a light guide
- a mirror
- a lens
- a detector

Light from the LEDs travels along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror.

The light is then directed through an aperture on the lens, from where it is focused onto the detector.

The light intensity detected is converted into electrical impulses.

These are processed by the instrument's microprocessor and converted into clinically meaningful results.

Instrument Checks

When the analyzer is first turned on, the instrument performs a series of electronic, signal and memory checks, as well as ensuring there is sufficient battery voltage to operate the instrument, if the instrument is powered by batteries.

Urinalysis Sequence

Each time a urinalysis strip is read, the instrument first positions the test table correctly and checks the electronics and signals.

It then takes reference readings off the white calibration bar on the test table. The reference readings are taken at six wavelengths and used to calculate the sample readings.

The table and test strip are pulled into the instrument where the correct placement of the test strip is confirmed. The table then moves completely into the instrument closing the shutter. The test table positions strip pads in the read area.

All test pads are read simultaneously at all six wavelengths. The analyzer's optical system images the entire strip, all reagent pads at once.

The light reflected from the test pad at specific wavelengths is dependent upon the degree of color change in the pad and is directly related to the concentration of the particular constituent in the urine.

The test and reference readings are then used to determine presence and/or amount of each constituent in the urine sample.

Appendix E: Symbols

This appendix provides the symbols for the analyzer and packaging.

Analyzer and Labeling Symbols

The analyzer and labeling symbols are in the following locations:

- CLINITEK Status+ analyzer documentation
- CLINITEK Status+ analyzer exterior
- Power supply provided with the analyzer
- Carton in which the analyzer was delivered
- Urinalysis strips and cassettes supplies that you use with the analyzer

Analyzer and Packaging Symbols

This following table contains the symbols that appear on the exterior of the CLINITEK Status+ analyzer, the power supply provided with the analyzer, the carton in which the analyzer was delivered, and the urinalysis strips and cassettes supplies that you use with the analyzer.

Symbol	Description
	Direct current input supply
	Double insulated product or transformer may also identify class 2 equipment (power supply only)
	Instrument is safety tested by TUV SUD, a national certification body, for conformity to global markets, including Canada, US, and Europe.
	Product complies with the applicable directives of the European Union
	Manufacturer
	European authorized representative
	Power on/off button

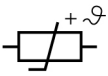
Symbol	Description
	Caution, consult accompanying documents
	*In vitro* diagnostic medical device
	Consult instructions for use
	Caution, temperature hazard, hot surface
	Caution for handling electrostatic sensitive devices to avoid causing a hazard to the product

Analyzer Symbols

This following table contains the symbols on the exterior of the CLINITEK Status+ analyzer and the carton in which the analyzer is delivered.

Symbol	Description
	Serial port
	This analyzer contains certain toxic or hazardous substances or elements. The environmental protection use period for this analyzer is 50 years. The analyzer can be used safely during its environmental protection use period. The analyzer should be recycled immediately after its environmental protection use period has expired.
	Temperature limitation (18–30° C)
	Contents sufficient for (n) tests (100)
	Use by YYYY-MM
REF	Catalog number
SN	Serial number

Symbol	Description
	Batch code
	Biohazard
	This equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements
	Printed on recycled materials
	Indicates compliance with the RESY packaging standards
	Do not reuse a reagent
	Keep this way up
	Fragile, handle with care
	Keep dry
	Keep away from sunlight and heat
	VDE Testing and Certification Institute – Germany
	Manufacturer's mark (FWHK) and manufacturing location (Hong Kong)
	Manufacturer's mark (FWGB) and manufacturing location (Geratebau, Germany)

Symbol	Description
	Encapsulated safety isolating transformer (short-circuit proof)
	**Positive Temperature Coefficient (PTC)** A thermistor device used to protect the transformer from short-circuits or overload. This is an auto reset device
	**Thermal cut-out (TCO)** This safety device disconnects the supply voltage to the transformer at a specific temperature. The operation temperature is stated below
	**Ingress protection rating** Protected against the entry of solid objects >1 mm but no protection from liquids
	Risk of electric shock.

Display Icons

This following table contains the icons that display on the screen.

Symbol	Name	Description
	Instrument Set Up	Allows you to set up the analyzer to suit your needs.
	Strip Test	Runs a test with a urinalysis strip (such as Multistix 10SG) urinalysis test and displays the strip test results.
	Cassette Test (not for self-test)	Runs a test with a cassette (CLINITEST hCG) test and displays the cassette test results.
	Results Recall	Recalls results from the analyzer memory.
	Printer	Prints results.

Symbol	Name	Description
	Data Transfer to Personal Computer	Displays the individual data and test results that the CLINITEK Status+ analyzer transfers to a PC.
	Alert	Alerts you to an error message.
	Battery Power	Displays a maximum of four bars, indicating the battery power level of a a battery powered analyzer.
	Low Battery Power	Displays fewer than three bars, indicating the battery power level of a a battery powered analyzer is low.
	Paper Out	Displays when you need to replace the printer paper or label roll.
	Connector	Indicates that the analyzer is connected to the CLINITEK Status connector.
	No Connector	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the CLINITEK Status+ analyzer is not connected to the CLINITEK Status connector.

Symbol	Name	Description
	Connectivity	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the CLINITEK Status+ analyzer is connected to the CLINITEK Status connector, Connectivity is enabled, and the system is connected to the LIS.
	No Connectivity	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the CLINITEK Status system is not connected to the wired (Ethernet) or wireless connection between the analyzer and the server on a remote computer.

Appendix F: Glossary

The glossary contains hardware and software terms and acronyms.

Hardware Terms

The following table defines hardware terms commonly used on the CLINITEK Status+ analyzer.

Term	Definition
bar code	Encoded information that is read by an optical scanner.
calibration bar	The white calibration bar (on the test table) that provides traceable calibration.
cassette	A CLINITEST hCG reagent cassette for pregnancy test use. (Not for self-test)
check cassette	A system diagnostic cassette that simulates a reacted test area. (Not for self-test)
CLINITEK Status+ analyzer	The CLINITEK Status analyzer with increased memory and additional features.
connector	The CLINITEK Status connector platform where you can attach the CLINITEK Status+ analyzer.
display	The LCD that displays the software user interface.
Ethernet port	The port where a network Ethernet cable is inserted.
external bar-code reader	An optional bar-code scanner that is connected to the RS232 port on the connector. Used to enter data.
external printer	An optional printer is connected to the CLINITEK Status Connect system, only when you connect the CLINITEK Status+ analyzer to the CLINITEK Status connector.
hardware	The physical components of the analyzer.

Term	Definition
instrument	The CLINITEK Status+ analyzer.
memory card	An electronic storage device that stores the analyzer software.
onboard printer	The internal paper roll printer.
onboard printer cover	The portion of the case that opens and closes to cover the on-board printer.
power cord	The cord that connects the analyzer to an electrical outlet.
power switch	The switch that turns the analyzer on and off.
serial connector	An RS232 connection used to transfer data between the analyzer and a PC.
test table	The plastic tray that holds the test table insert.
test table insert	The plastic case that holds the urinalysis strip for testing.
touch screen	The LCD display that lets the operator select controls on the screen.
USB port	The ports where USB cables are inserted.
urinalysis strip	A Siemens urinalysis strip with test pads for *in vitro* diagnostic use.

Software Terms

The following table defines software terms commonly used on the CLINITEK Status+ analyzer.

Term	Definition
alert message	A message that conveys information to the operator about the analyzer.
alphanumeric	Data comprised of alphabetic and numeric characters.
audio alert	Sounds emitted by the analyzer to draw the operator's attention to the analyzer.

Term	Definition
authorized operator	Operators who can perform certain tasks, where they gain access to the analyzer by entering their operator ID to perform those tasks.
auto-check	Performs automatic strip quality checks and provides results in about 1 minute.
automatic strip identification	Automatically identifies an ID band strip type with no need to select it from a menu.
baud rate	The speed of data transmission in bits per second (bps) between the analyzer and a remote device.
calibration	The analyzer reads the white calibration bar at the appropriate wavelengths to ensure accurate test results.
cancel	To end a sequence or an operation.
comment	A notation the operator enters for a QC test result.
configuration	System hardware and software settings that adjust or configure some aspect of the analyzer.
conventional unit	Unit of measurement for test results.
control	Objects that display on the software UI that the operator can manipulate. Buttons, boxes, and option buttons are examples of controls. Solution containing a known level of analytes.
countdown	A numeric display that indicates the amount of time left in an operation.
Custom set up	Patient, operator, and sample appearance custom settings.
data entry	The act of entering data such as a patient or operator ID into the analyzer.
data entry box	A software UI object which displays the data that the operator entered.

Term	Definition
default setting	A value defined and preset by Siemens.
delete	A function an operator uses to remove an object, such as test results or an authorized operator, from the system database.
diagnostic screen	A software UI screen which enables the operator to perform a system diagnostic test when troubleshooting the analyzer.
disabled	The state when a software feature or function, such as a configuration setting, is not available.
enabled	The state when a software feature or function, such as a configuration setting, is available.
error	An event that prevents the analyzer from operating as expected.
error code	A number displayed by the analyzer to communicate the occurrence of an error to the operator.
export	To copy setup data from the analyzer to a removable data storage device.
Full Test	A strip or cassette test where the operator is prompted to enter patient and operator information.
help	Information presented to the operator to assist them with the completion of a task or operation.
Help screen	The screen that displays the help information to the operator.
humidity check	Detects if the strip is exposed to humidity and if so, displays an error message.
icon	An graphical depiction of a control in the software UI.
import	To copy setup data from a removable data storage device to the analyzer.

Term	Definition
keyboard	A software UI display (alphabetic or numeric) that the operator uses to type information.
laboratory information system	Laboratory computer system that you can connect to the analyzer. Abbreviation: LIS.
Menu screen	A software UI screen that displays a list of commands and one or more command buttons for the operator to select.
Normal System	Provides a negative result or a value for a positive result.
notifications message	A message that conveys information about the analyzer to the operator.
navigation	The act of moving between the screens that comprise the analyzer software UI.
navigation button	A software UI button control that when selected, brings the operator to a different software UI screen.
parity	A serial communication setting that verifies whether the data has been transmitted accurately.
Plus System	Provides plus symbols (+) for a result. The more plus symbols, the higher the result. For example, 2 + represents two plus symbols (++) and 3+ represents three plus symbols (+++).
power supply	Electronic component of the analyzer that converts the AC voltages in the power line to the DC voltages inside the analyzer.
prompt	Questions, instructions, or commands that help the operator complete the current task.
quality control	A process that ensures the operator is following the procedure to obtain accurate test results. Abbreviation: QC.
Quick Test	A strip or cassette test where the analyzer does not prompt you to enter patient or operator information.

Term	Definition
ready	The state when the analyzer is available to perform tests.
recall	To access data such as test results stored on the analyzer.
restore	To restore the analyzer setup to the default settings.
required entry	A data entry box that must have data entered into it.
sample interference notes	Informs the user when appropriate about test results that can be affected by components detected in the same urine sample.
screen	The display area that contains the controls the operator selects when operating the analyzer. The analyzer software UI contains screens, prompts, messages, and other operating information.
screen title	A text label that typically displays in the upper left corner of a screen which serves as a label for that screen.
Select Ready screen	The software UI screen that displays when the system completes the startup process. All software UI navigation begins from the Select Ready screen.
settings	The areas of the software user interface where you can configure the analyzer.
Settings screen	A software UI screen which enables the operator to adjust or configure some aspect of the analyzer.
SI units	An abbreviation for Systéme International, a unit of measure.
software	Computer instructions that generate and carry out commands to control the system operation.

Term	Definition
startup code	If your software provides sample interference notes, the Start-Up wizard prompts you to enter a startup code.
Start-Up Wizard	A wizard that steps you through a quick setup procedure when you power on the analyzer for the first time.
stop bits	The number of bits that maintain synchronization between the system and a remote device during data transmission.
test result	Measured reportable values displayed to the operator at the end of a test sequence.
test sequence	A series of software UI screens that guides the operator through the tasks required to perform a test on a sample.
Title bar	The area along the top of software UI screens where the location icon and title display.
troubleshooting	Determining the cause of a system or test performance problem.
user interface	The system software screens where the operator interacts. Abbreviation: UI.

Acronyms

The following table defines acronyms commonly used on the CLINITEK Status+ analyzer.

Acronym	Full Title
ALB	Albumin
ASTM	American Society for Testing and Measurement
BIL	Bilirubin
BLO	Occult Blood
CRE	Creatinine
CSV	Comma Separated Values

Acronym	Full Title
GLU	Glucose
hCG	Human Chorionic Gonadotrophin (Not for self-test)
KET	Ketone
LAN	Local Area Network
LEU	Leukocyte
NIST	National Institute of Standards and Technology
NIT	Nitrite
pH	Hydrogen ion concentration
PC	Personal Computer
PRO	Protein
QC	Quality Control
SG	Specific Gravity
SI	Systéme International
SN	Serial Number
UI	User Interface
URO	Urobilinogen
USB	Universal Serial Bus
VA	Volt Amp

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